DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-972/S-021

Wyeth Laboratories
Attention: Ms. Mary Alice Dankulich
170 North Radnor Chester Road
St. Davids, PA 19087

Dear Ms. Dankulich:

Please refer to your November 17, 2000 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) Tablets, 200 mg.

We note that this supplement was submitted as a "Special Supplement - Changes Being Effected" under 21 CFR 314.70 (c)(2).

This supplemental new drug application provides for final printed labeling revised under the **ADVERSE REACTIONS** section to include the adverse drug event terms: myopathy, hemolytic anemia, and aplastic anemia.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your November 17, 2000 submission). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Raymond Lipicky

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